



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,892	08/20/2003	Michael C. Bednarck	11531US.01	8201

33486 7590 01/22/2007
HEIMBECHER & ASSOC., LLC
P O BOX 33
HAMEL, MN 55340-0033

EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
----------	--------------

3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/645,892	Applicant(s) BEDNAREK, MICHAEL C.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-24 and 26 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on November 6, 2006. The objection to the drawings and 35 U.S.C. 112, second paragraph rejections of claims 16 and 17 are withdrawn. The prior art rejections of claims 1 and 18 using Sun in view of Swanson are maintained. All other prior art rejections are withdrawn. Upon further consideration, however, new grounds of rejection of are made.

Claim Objections

Claims 1-24 are objected to because of the following informalities: Regarding claim 1, lines 2 and 4, applicant should amend to recite "outer tubular surface" to correct the lack of antecedent basis in line 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson (U.S. Pat. No. 5,582,609).

Regarding claim 1, Swanson discloses an ablation catheter comprising:

a catheter shaft defining an inner surface 12 and an outer surface 56 (Fig. 13B);

Art Unit: 3739

at least one braided electrode E_{CON} interposed in a fixed position between the inner surface and the outer surface (col. 7, ln. 55-61 and Fig. 13B); and

the outer tubular surface 56 defining at least one electrode aperture such that a portion of the electrode is exposed (Fig. 13B).

Regarding claim 16, Swanson further discloses that at least one braided electrode E_{CON} defines an electrode surface that is generally flush with the outer surface 56 of the catheter shaft (col. 12, ln. 24-33 and Fig. 13B).

Regarding claim 18, Swanson further discloses that the at least one electrode E_{CON} is configured to at least partially contact the tissue during use (col. 12, ln. 34-45 and Fig. 13B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13, 15, 19-23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609) and further in view of an alternate embodiment of Bednarek ('500).

Regarding claim 1, Bednarek discloses an ablation catheter comprising:
a catheter shaft defining an inner surface 20 and an outer surface 42 (Fig. 11);
at least one coiled electrode 46 interposed between the inner surface and the outer surface (Fig. 11); and
the outer tubular surface 42 defining at least one electrode aperture 38 such that a portion of the electrode is exposed (Fig. 11).

The claim differs from Bednarek in calling for the electrode to be a braided electrode. Swanson, however, teaches that a coil-type electrode alternatively can be made using braided wire (col. 7, ln. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a braided electrode in the device of Bednarek in view of the teaching of Swanson as an obvious alternate way of making a coil-type electrode.

The claim also differs from Bednarek in calling for the electrode to be in a fixed position. In an alternate embodiment, however, Bednarek teaches that the electrode may also be in a fixed position (col. 11, ln. 1-7 and Fig. 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have kept the electrode of Bednarek in a fixed position in view of an alternate embodiment of Bednarek as an obvious alternate way of using or constructing the device that is taught and suggested by the inventor.

Art Unit: 3739

Regarding claim 2, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses a lumen 39 within the catheter shaft (Fig. 11).

Regarding claim 3, Bednarek discloses the catheter of claims 1 and 2 in view of Swanson. In addition, Bednarek discloses the inner surface 20 of the catheter shaft defining at least one fluid aperture providing a fluid flow path past the electrode (col. 10, ln. 25-30). Since Bednarek discloses that fluid is introduced through lumen 39 so that fluid can flow through the electrode 46, there inherently must be at least one fluid aperture in the inner surface 20 to allow the fluid to flow through the electrode.

Regarding claim 4, Bednarek discloses the catheter of claims 1-3 in view of Swanson. In addition, Bednarek discloses an introduction system in fluid communication with the lumen 39, the introduction system configured to provide a fluid material to the lumen (col. 10, ln. 25-30).

Regarding claim 5, Bednarek discloses the catheter of claims 1-4 in view of Swanson. In addition, Bednarek discloses that the lumen 39 is configured to guide the fluid media through the at least one fluid aperture (col. 10, ln. 25-30 and the rejection of claim 3).

Regarding claim 6, Bednarek discloses the catheter of claims 1-5 in view of Swanson. In addition, Bednarek discloses that the at least one fluid aperture is located so as to guide the fluid media past the braided electrode substantially to move blood away from the braided electrode to lessen formation of coagulum (col. 10, ln. 25-30 and col. 13, ln. 47-49). Since the fluid of Bednarek flows through the electrode in the same

Art Unit: 3739

manner as disclosed by applicant, the location of the aperture inherently performs the claimed intended use.

Regarding claim 7, Bednarek discloses the catheter of claims 1-4 in view of Swanson. In addition, Bednarek discloses that the fluid media comprises a conductive fluid media (col. 4, ln. 6-10).

Regarding claim 8, Bednarek discloses the catheter of claims 1-4 and 7 in view of Swanson. In addition, Bednarek discloses that the conductive fluid media is configured to flow past the at least one braided electrode and conduct ablative energy to a target tissue (col. 4, ln. 6-10).

Regarding claims 9-11, Bednarek discloses the catheter of claims 1-4 and 7-8 in view of Swanson. In addition, ablation by ohmic energy, convection, and conduction is inherent to the device of Bednarek, since Bednarek uses an electrode with conductive fluid.

Regarding claim 13, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the electrode has a length of at least 0.4 cm (col. 10, ln. 20-21 and Fig. 11). Since 0.4 cm is a minimum length, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the electrode of Bednarek at least 1 cm as a matter of routine skill in the art that is in accordance with the parameters disclosed by Bednarek.

Regarding claim 15, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the at least one braided electrode 46

Art Unit: 3739

generally defines an electrode surface that is recessed below the level of the outer surface 42 of the catheter shaft (Fig. 11).

Regarding claim 19, Bednarek discloses the catheter of claim 1 in view of Swanson. In addition, Bednarek discloses that the catheter shaft defines a second lumen 23 (Fig. 11).

Regarding claim 20, Bednarek discloses the catheter of claims 1 and 19 in view of Swanson. In addition, Bednarek discloses a control wire 16 connected with the catheter shaft and located within the second lumen.

Regarding claim 21, Bednarek discloses the catheter of claims 1, 19, and 20 in view of Swanson. In addition, Bednarek discloses that the control wire is precurved to manipulate the catheter shaft such that the catheter shaft forms a substantially circular shape (col. 8, ln. 7-40 and Fig. 2).

Regarding claim 22, Bednarek discloses the catheter of claims 1 and 19-21 in view of Swanson. In addition, Bednarek discloses that the substantially circular shape is adapted to conform to the inner shape of the pulmonary vein. The device of Bednarek is inherently adaptable to conform to the inner shape of the pulmonary vein.

Regarding claim 23, Bednarek discloses the catheter of claims 1 and 19 in view of Swanson. In addition, Bednarek discloses that the at least one braided electrode is connected with at least one corresponding wire adapted to connect with an ablation energy source (col. 9, ln. 67 – col. 10, ln. 5).

Regarding claim 26, Bednarek discloses an ablation catheter in view of Swanson comprising:

a fixed braided electrode means 46 for forming an ablation lesion through contact with a target tissue;

catheter shaft means 22 for locating the braided electrode means adjacent the target tissue;

and lumen means 39 for channeling a fluid media past the braided electrode means.

See Fig. 11 and the preceding rejection of claim 1.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609) and further in view of Swartz (U.S. Pat. No. 6,080,151).

Regarding claim 24, Bednarek discloses the catheter of claims 1, 19, and 23 in view of Swanson. In addition, Bednarek discloses at least one separate lumen to accommodate the at least one wire for connecting the electrode to the ablation energy source (col. 9, ln. 67 – col. 10, ln. 5). Bednarek does not specify that the at least one wire is routed through the second lumen as claimed. Swartz, however, teaches routing the electrode wires through a second lumen 29 that also includes a control wire 24 in order to keep the wires separate from the fluid delivery lumen 18 (Figs. 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have routed the electrode wire of Bednarek through the second lumen with the control wire in view of the teaching of Swartz in order to keep the wires separate from the fluid delivery lumen.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U.S. Pat. No. 6,120,500) in view of Swanson (U.S. Pat. No. 5,582,609) and further in view of Swartz (U.S. Pat. No. 6,080,151).

Regarding claim 12, Bednarek discloses the catheter of claim 1 in view of Swanson. The claim differs from Bednarek in calling for the at least one braided electrode aperture to have a length in the range of about 1 centimeter to about 10 centimeter. Swartz, however, discloses an analogous ablation catheter with electrode apertures 20 that he teaches can be of any size or shape that permit the passage of the conductive media through the lumen of the catheter without compromising the structural integrity of the catheter (col. 7, ln. 54-62 and Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apertures of Bednarek have a length of at least 1 cm in view of the teaching of Swartz since Swartz teaches that it is obvious to vary the aperture size.

Regarding claim 14, Bednarek discloses the catheter of claim 1 in view of Swanson. The claim differs from Bednarek in calling for the at least one braided electrode aperture to have a width in the range of about 60 degrees to about 180 degrees. Again, Swartz, discloses an analogous ablation catheter with electrode apertures 20 that he teaches can be of any size or shape that permit the passage of the conductive media through the lumen of the catheter without compromising the structural integrity of the catheter (col. 7, ln. 54-62 and Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apertures of Bednarek have a width in the range of about 60 degrees to about

Art Unit: 3739

180 degrees in view of the teaching of Swartz since Swartz teaches that it is obvious to vary the aperture size.

Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun (WO 00/78239) in view of Swanson (U.S. Pat. No. 5,582,609).

Regarding claim 1, Sun discloses an ablation catheter comprising:

a catheter shaft defining an inner surface 22 and an outer surface 172 (Fig. 9c);

at least one electrode 46 interposed between the inner surface and the outer surface (pg. 33, ln. 11-21 and Fig. 9c); and

the outer tubular surface defining at least one electrode aperture such that a portion of the electrode is exposed (Fig. 9c).

The claim differs from Sun in calling for the electrode to be a braided electrode. Swanson, however, teaches using a braided electrode (col. 7, ln. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a braided electrode in the device of Sun in view of the teaching of Swanson as an obvious alternate type of electrode that well-known in the art.

Regarding claim 18, Sun discloses the catheter of claim 1 in view of Swanson. In addition, Sun discloses that the at least one braided electrode is configured to at least partially contact the tissue during use (Fig. 8c).

Allowable Subject Matter

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the prior art rejections of claims 1 and 18 using Sun in view of Swanson have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, in the knowledge generally available to one of ordinary skill in the art, braided ring electrodes are well-known in the art. The reference to Swanson is used as an illustrative example to teach this point. Furthermore, both Sun and Swanson teach shielding ring electrodes with an insulating material (Fig. 9c of Sun and Fig. 13B of Swanson). Clearly, these two structures and teachings are analogous. Therefore, at the time the invention was made, it would have required only routine skill in the art to use a braided ring electrode instead of a solid ring electrode in the device of Sun in view

of the teaching of Swanson as an obvious alternate and equivalent type of ring electrode that is well-known in the art. Finally, applicant has not disclosed any criticality or unexpected result associated with a braided ring electrode versus a solid ring electrode.

In response to applicant's argument that Sun fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a lumen or a conductive medium) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that Sun does not disclose an "outer tubular surface" as claimed. Applicant goes on to argue that: "One of ordinary skill in the art would understand the term "tubular" to relate to "tubes" which are generally understood to be cylinders. ... The alleged "tubular surface" of Sun is, at best, a half-cylinder, which does not comport with any generally understood definition of a tube" (pg. 12 of applicant's Remarks).

In response, the examiner maintains that "tubular", in the broadest reasonable sense, merely corresponds to something that resembles a tube shape. Therefore, the half-pipe surface of Sun resembles a tube shape. The examiner also traverses applicant's contention that a tube is the same thing as a cylinder. By definition, a cylinder has top and bottom surfaces in parallel planes. A tube may be open on both sides.

Moreover, in claim 14, applicant recites that the aperture in said outer tubular surface has a width of up to about 180 degrees. (See also pg. 15, ¶ 60 and Fig. 3A of applicant's specification). This means that applicant's claimed outer tubular surface with an aperture width of 180 degrees is a half-pipe shape. Therefore, the examiner maintains that Sun is in accordance with the "outer tubular surface" as claimed.

Applicant further argues that Sun does not disclose an "aperture" as claimed. Applicant goes on to argue that: "an "aperture" in a tube suggests a hole or port with defined, circumscribed sides" (pg. 12 of applicant's Remarks).

In response, the examiner maintains that an "aperture", in the broadest reasonable sense, is merely an opening or a gap. Therefore, the half-pipe shape of the exposed electrodes 46 of Sun (Fig. 9c) is an "aperture" in the "outer tubular surface" 172 because it constitutes an opening or gap that was purposely constructed and that would not be there if the outer tubular surface 172 covered the entire surface of the electrodes 46.

In response to applicant's argument that Sun fails to show certain features of applicant's invention, the applicant is again reminded that the features upon which applicant relies (i.e., a hole or port with defined, circumscribed sides) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The preceding remarks regarding the "outer tubular member" and "aperture" also apply to the new grounds of rejection under 102(b) using Swanson.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
1/12/07

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER